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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,740	12/27/2001	Bradley J. Enegren	PF00434 US	1376

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MEDTRONIC MINIMED INC.
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EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/21/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,740

Applicant(s)

ENEGREN ET AL.

Examiner

Robert L. Nasser

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 12-20 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 8 and 11 are objected to because of the following informalities: Both claims refer to the connector fitting, which was defined in claim 2. However, these claims depend from claim 1. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 8-10, and 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfeiffer. Pfeiffer shows a device including a catheter having a sensor 7 with a sensor tip 4a and a flush sleeve, the outer wall of channel 1, which is "generally" concentric" with sensor 7. The catheter houses channels 2 which carries fluid to tip 4a to clean the tip. The flush sleeve is tight fit to the sensing device. In addition, it runs from the proximal to the distal end of the sensor. There is also a connector 20 or 21 which receives the sensor and which is affixable internally. Again, any fluid could be used, as discussed above. In addition, there is a one way valve 13.

Claims 1, 4, 6, 9, 10, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Koning et al. Koning shows a catheter having a sensor tip that is for direct contact with body fluids, a flush sleeve, the entire outer catheter surrounds the sensor in a generally concentric way, where the outer catheter has a channel 14 that which carries calibration fluid (which is also a flushing fluid) to the sensor tip, where the sensing tip is in a tight fit relationship to the flush sleeve.

Claims 1, 2, 4, 6-10, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyasaka et al. Miyasaka et al shows a device having an outer sleeve 21 that surrounds a sensor 3 concentrically, receives fluid from a infusion pump 42, which fluid contains both saline and an anticoagulant, where the member 21 connects to a connector 13, which is affixable internally. Connector 13 is affixable internally, in that it is capable of being fixed internally. The device further includes a protective sleeve 11, which contains therein a fluid conduit and the sensor.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyasaka et al in view of Borsanyi. Borsanyi further teaches that he conventional method of introducing fluid into a pressure measuring line is through a septum 37. Hence, it would have been obvious to modify Miyasaka et al to use such a septum, as it is merely the substitution of one known fluid delivery technique for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer in view of Mills et al. Pfeiffer is a catheter that transmits signals to the exterior of the body via a hard connection. Mills et al shows a similar pressure measuring catheter that teaches that a wireless connection is an alternate way of communicating patient data to a monitor. Hence, it would have been obvious to modify Pfeiffer to use a wireless transmitter, as it is merely the substitution of one known equivalent in the art for another.

Applicant's arguments filed 1/27/2004 have been fully considered but they are not persuasive.

With respect to the Pfeiffer and Koning references, applicant has asserted that the sensor and the outer tube are not generally concentric or on a generally common axis. The examiner disagrees, noting that the term "generally" is broad. It is the examiner's position that the lumens in question are Generally concentric, even though they are not concentric.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

All of Smith, Hok, Engstrom et al, and Porter show sensors that are surrounded by outer lumens, i.e. flush sleeves, where the sensor and the outer lumen is concentric.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

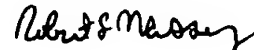
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736



ROBERT L. NASSER
PRIMARY EXAMINER

RLN
April 19, 2004